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09/837,714	04/18/2001	Daniel A. Japuntich	48317USA3M.032	9172

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/837,714	Applicant(s) DANIEL A. JAPUNTICH ET AL.
	Examiner AARON J. LEWIS	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 7, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 33, 35-42, 44, 46, 49, 50, 55-59, and 64-66 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 33, 35-42, 44, 46, 49, 50, 55-59, and 64-66 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 33,44,46,49-50,55-59,64,65,66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al.('516) in view of McKim('618).

As to claim 33, Simpson et al. disclose a method of making a filtering face mask which method comprises: providing a valve seat that comprises an orifice (16) and a seal surface, wherein the orifice allows exhaled air to pass therethrough and being surrounded by the seal surface; and a single flexible flap (15), supporting the single flexible flap non-centrally and operatively relative to the orifice of the valve seat to form an exhalation valve and attaching the exhalation valve to the mask body that is adapted to fit over the nose and mouth of a person (fig.1).

The differences between Simpson et al. and claim 33 are supporting the single flexible flap such that the flap assumes, in its closed state, a curved profile in a cross-sectional view thereof, which the curved profile comprises a curve that extends from a first point where a first stationary portion of the flexible flap is supported on the valve seat to a second point where a second free portion of the flap is pressed against the seal surface of the valve seat in a closed state of the exhalation valve, and the second free portion of the flexible flap is held in its closed state under

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any orientation of the valve, at least in part, by virtue of the curved profile thereof; and the second free portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass through the orifice and to provide an open state of the exhalation valve to make the flexible flap out of contact with the seal surface at the second point while the first portion of the flexible flap remains essentially stationary at the first point;

McKim (figs. 1 and 2) teaches supporting the single flexible flap such that the flap assumes, in its closed state, a curved profile in a cross-sectional view thereof, which the curved profile comprises a curve that extends from a first point where a first stationary portion (14a) of the flexible flap is supported on the valve seat to a second point where a second free portion of the flap is pressed against the seal surface of the valve seat in a closed state of the exhalation valve, and the second free portion (29) of the flexible flap is held in its closed state under any orientation of the valve, at least in part, by virtue of the curved profile thereof; and the second free portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass through the orifice and to provide an open state of the exhalation valve to make the flexible flap out of contact with the seal surface at the second point while the first portion of the flexible flap remains essentially stationary at the first point. McKim teaches the positioning of the flexible flap in this configuration for the purpose of seating quickly, effectively and without float or bounce after each opening (col. 1, lines 64-72).

It would have been obvious to modify the exhalation valve of Simpson et al. to be mounted to the valve seat such that the one free portion (opposite the fixed portion #14a as illustrated in fig. 3

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of McKim) of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice for because it would have provided for seating quickly, effectively and without float or bounce after each opening as taught by McKim.

As to claim 44, the shape of the orifice (16) of Simpson et al. does not fully correspond to the shape of the seal surface and the flexible flap (15) is mounted to the valve seat in cantilever fashion.

As to claim 46, the curvature of the flexible flap of Simpson et al. as modified by McKim extends from a plurality of points where the flap is affixed to the valve seat to a plurality of points which are opposite the plurality of points on the fixed portion of the flexible flap.

As to claim 49, the relative dimensions and spacing of the constituents of the exhalation valve of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative spacing including 1-3.5 mm between the flap retaining surface and the orifice because of the use of different sizes of valves in an effort to accommodate different sized wearers.

As to claim 50, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including a relatively light weight plastic. Inasmuch as Simpson et al. (page 2, lines 37-65) disclose the valve flap being made from plastic and/or rubber material, it would have been obvious to make the valve

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seat from any well known material which would achieve known or expected results including a plastic and/or rubber material because the use of a valve seat of the same material as the valve flap would have provided for more effective physically cooperation.

As to claim 56, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

As to claim 55, the second free portion of the flexible flap of Simpson et al. as modified by McKim has a profile that when viewed from the front corresponds to the general shape of the seal surface and comprises a curve (figs.1 and 2 of McKim).

As to claim 57, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

As to claim 58, the flexible flap of Simpson et al. is positioned on the valve such that exhaled air deflected downward during an exhalation when the filtering face mask is worn on a person (fig. 1 of Simpson et al.).

As to claim 59, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

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As to claim 64, the exhalation valve of Simpson et al. (fig.1) is positioned on the mask body substantially opposite to a wearer's mouth and such that the second free portion of the flexible flap resides beneath the stationary portion when the mask is worn on a person.

New claims 65 and 66 are substantially equivalent in scope to claim 33 and are included in Simpson et al. as modified by McKim for the reasons set forth above with respect to claim 33.

3. Claims 35-38,41,42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33,44,46,49-50,55-59,64,65,66 above, and further in view of Shindel ('277).

The difference between Simpson et al. as modified by McKim and claim 35 is securing a valve cover to the valve seat, wherein the valve seat includes a flap retaining surface, and the flap retaining surface is located within an internal chamber defined by the valve cover.

Shindel (col.2, lines 59-66) teaches a valve securing device in the form of a valve cover (7) that is disposed over the valve seat and that comprises a surface (14) that mechanically holds flexible flap (6) against the flap retaining surface (5) in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where the flexible flap is mechanically held against the flap retaining surface being located off center (fig.2) relative to the flap. Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices.

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It would have been obvious to further modify the manner of attachment of the exhalation valve of Simpson et al. to employ a cover over the valve seat because it would have provided a simple arrangement with ready removability of the cover when desired and because it would have provided protection for the exhalation valve as taught by Shindel.

As to claim 42, the flexible flap of Simpson et al. as modified by McKim (figs.1 and 3) would normally assume a flat configuration but is curved by virtue of its securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

As to claims 36 and 37, the first stationary portion of the flexible flap of Simpson et al. as further modified by Shindel is held (via mechanical clamping) between the flap retaining surface (#5 of Shindel) on the valve seat and a second member (#14,15 of Shindel) that is associated with the valve cover when the valve cover is secured to the valve seat.

As to claim 38, the flexible flap of Simpson et al. as modified by McKim (figs.1 and 2) teaches that the flexible flap can assume a curved profile, when in its closed state, that extends in from where the flexible flap contacts the second member of the valve cover to where the second portion of the flexible flap contacts the seal surface of the valve seat.

As to claim 41, the flexible flap of Simpson et al. as modified by McKim (figs.1 and 3) would normally assume a flat configuration but is curved by virtue of its securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

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Allowable Subject Matter

4. Claims 39 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments filed 07/02/2002 have been fully considered but they are not persuasive.

The Castiglione affidavit contends that the valve flap of Simpson et al. must rely of negative inhalation pressure to maintain a closed position is disagreed with because there is no disclosure in Simpson et al. which suggests such a requirement. On the contrary, Simpson et al. fig.3 clearly illustrates valve flap (14) being resiliently held in a closed position against knife edge sealing surfaces (19) thereby providing a clear teaching of a seal between the valve flap and valve seat during before the mask is donned. Further, Simpson et al. (page 1, lines 39-64 and page 2, lines 29-32) disclose that the mask is intended to filter harmful vapors (a function which cannot be accomplished while an exhalation valve is dangling open), that the mask includes an exhalation valve(s) located on portion (1, upper side) and/or portion (2, lower side) of the mask, that the exhalation valve(s) are intended to materially reduce the buildup of water vapor and that while the exhalation valve(s) may leak it is clear from the disclosure that they are not intended to leak. Therefore, in view of the the disclosure as a whole, one of ordinary skill could not conclude that

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the exhalation valve(s) of Simpson et al. would require negative inhalation pressure in order to remain in a closed position.

Applicant's assertion that the exhalation valve flap would dangle open responsive to gravitational forces even if accurate does not distinguish from Simpson et al. because if the exhalation valve of fig.2 were located within portion #1 (upper portion) of the mask as illustrated in fig.1 and as disclosed by Simpson et al. at page 2, lines 29-32, then by applicant's own reasoning the valve flap would remain in the closed position due to gravitational forces until being subjected to the pressure of exhalation by a wearer.

The Affidavit of David M. Castiglione is insufficient to overcome the above prior art rejection because: the declaration provides no objective evidence that the valve of fig.2 of Simpson et al. cannot remain closed without negative pressure within the mask based upon an actual physical inspection and comparison of the prior art device (Simpson et al.) to the device of the instant invention as claimed. Affiant concludes that the valve of fig.2 requires negative pressure within the mask in order to remain closed based upon a reading of the specification of Simpson et al. rather than on actual objective testing of the prior art device.

As to the Bowers, Fabin, Castiglione and Betts affidavits, the individual arguments that McKim constitutes nonanalogous art because it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed.

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Cir. 1992). In this case, it is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col.1, lines 64-72).

Applicant's argument that the valve of McKim lacks the required flexibility of applicant's invention is noted; however, it is submitted that the valve of Simpson et al., being an exhalation valve, exhibits structure which is fully capable of providing such a function. Further, no particular degree of flexibility is quantitatively and/or structurally defined in any of the claims of the instant application.

Applicant's arguments that the prior art does not provide the benefits of applicant's invention is disagreed with because the prior art does teach the claimed structure of the instant application and as such, is fully capable of providing the so called benefits.

Applicant's argument that the propriety of the combination is not proper is disagreed with because the reasons for modification of Simpson et al. are clearly set forth above in the body of the rejection(s) of the claims.

Accordingly, the affidavits by Bowers, Fabin, Castiglione and Betts are insufficient to overcome the prior art rejection set forth herein above based upon a conclusion that they do not believe that one of ordinary skill would be motivated to combine the teachings of McKim with

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Simpson et al. to achieve the valve of the instant invention. It is submitted that one of ordinary skill having possession of the prior art to Simpson et al. and McKim which clearly teaches nonaligned mounting of a valve flap in order to achieve effective sealing would suggest an answer to the problem of how to prevent accidental valve opening and efficient sealing between inhalation and exhalation.

6. Applicant's arguments filed 01/07/2003 have been fully considered but they are not persuasive.

Applicant's assertions that the valve of fig.2 of Simpson et al. dangles open are not persuasive. The mask of Simpson et al. is specifically intended to filter gaseous or vaporous contaminants and particulate contaminants (page 1, lines 16-28 and lines 79-84) and is intended for use in noxious atmospheres (page 1, lines 58+). The valve of fig.2 is expressly disclosed as opening responsive to a wearer's exhalation (page 2, lines 38-50). One of ordinary skill would not conclude that the exhalation valve of fig.2 would dangle open under any conditions of proper use because the mask would not function as it is disclosed and intended to operate.

To the extent, if any, that the valve of fig.2 of Simpson et al. may dangle open, the combination of Simpson et al. as modified by McKim would assure that the valve flap of Simpson et al. as modified by McKim would remain sealed against its seat due to its prestressed configuration until a wearer exhaled.

Applicant's arguments regarding whether McKim constitutes analogous art have been addressed herein.

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Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

March 24, 2003



Aaron J. Lewis
Primary Examiner